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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,514	01/04/2007	Marlene Mueller	10460.204-US	2963

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NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER

GOUGH, TIFFANY MAUREEN

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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11/13/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No. 10/565,514	Applicant(s) MUELLER, MARLENE	
	Examiner TIFFANY M. GOUGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-37 is/are pending in the application.
- 4a) Of the above claim(s) 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed 6/29/2009 has been received and entered into the case. Claims 20-37 are pending.

Claims 36,37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claims 20-35 have been considered on the merits.

Claims 20-35 have been considered on the merits. All amendments and arguments have been fully considered.

The previous rejection over claims 24 and 25 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been **withdrawn** in light of applicants claim amendments.

The previous rejection over claims 20, 21, 33 and dependent claims 22-32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been **withdrawn** in light of applicants claim amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20-24, 26-35 stand rejected under 35 U.S.C. 102 (e) as being anticipated by Bisgaard-Frantzen et al. (US 2004/0023349 A1).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Bisgaard-Frantzen teach a process of enzymatic saccharification wherein an alpha-amylase liquefied starch product (0030-0034) is treated with a polypeptide having glucoamylase activity (0017, 00370-0040) at temperatures between 50-80 for 0.5-36 hours at a pH from 5.5-6.2 (0017, 0055-56). The polypeptide is added in an amount of 0.01-0.5 AGU/g DS (0040). The saccharification product is prepared by dry milling of whole grains (0015). The saccharification step is followed by a yeast fermentation step (0018-0019).

Thus, the reference anticipates the claimed subject matter.

Response to Arguments

Applicant's arguments filed 6/29/2009 have been fully considered but they are not persuasive. Applicant argues that the process conditions are not disclosed by Bisgaard-Frantzen ('349), although the references disclose condition ranges which overlap with applicants claimed ranges. Applicant argues that a case by case determination must be made.

It is the examiner's position that saccharification processes are well known to those of ordinary skill in the art as exemplified by '349 at (0057) who teach that various modifications are apparent to those skilled in the art and such modifications fall within the scope of invention of '349. Clearly applicants claimed pH of from 5.5 to 6.2 falls within the disclosed pH of '349 who teach about 4 to about 7, the claimed temperature of 50 to 80°C falls within the disclosed temperature of 40-60°C of '349. In addition, applicants claimed time period of 0.5 to 36 hours fall within '349s disclosed time period

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of about 2 to about 60 hours. There is nothing of record to show that the disclosed ranges of '349 would not result in a process of enzymatic saccharification as claimed by applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-35 stand rejected under 35 U.S.C. 103(a) as being obvious over the combination of each of Veit et al. (US 2004/0091983 A1) or Veit et al. (WO 02/38787 A2) or Olsen et al. (WO 02/074895 A2) or Olsen et al. (US 2004/0115779 A1) or Veit (US 20020006647 A1) in view of Nielsen et al (6255084).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject

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matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Applicant claims a method of enzymatic saccharification or pre-saccharification wherein the starch containing material is treated with a polypeptide at a pH from 5.5-6.2 at a temperature of 50-80°C for 0.5-36 hours. The polypeptide may be an alpha-amylase or glucoamylase from a fungal organism. Applicant also claims the saccharification step to be followed by yeast fermentation.

The references teach method of enzymatic saccharification or pre-saccharification wherein the starch containing material is treated with a polypeptide at a temperature of 50-80°C for 0.5-36 hours. The polypeptide may be an alpha-amylase or glucoamylase from a fungal organism. They also teach the saccharification step to be followed by yeast fermentation.

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The references do not teach saccharification or pre-saccharification at a pH from 5.5-6.2.

Nielsen et al (6255084) teach thermostable glucoamylases from *Talaromyces emersonii* used for starch conversion, i.e. saccharification processes (abstract, col. 4, lines 10-12) at temperatures from 60-80°C and a pH of 5.5 (col. 7, lines 10-22).

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the glucoamylase of Nielsen in a saccharification method such as those taught by Veit and Olsen because Nielsen teach their glucoamylase to be active at higher temperatures and pH than that of most commercially used glucoamylases (col. 1, lines 44-53, col. 7, lines 5-40) and requires a lesser amount of glucoamylase to be used due to its thermostability.

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to have used a glucoamylase such as that taught by Nielsen with a reasonable expectation for successfully carrying out a saccharification process because Nielsen teach the use of a glucoamylase in a saccharification process. They teach their glucoamylase to be active at higher temperatures and pH than that of most commercially used glucoamylases (col. 1, lines 44-53, col. 7, lines 5-40) and requires a less amount of glucoamylase to be used due to its thermostability.

Response to Arguments

Applicant's arguments filed 6/29/2009 have been fully considered but they are not persuasive. In response to applicants argument regarding same assignment of references '983 and '779, applicant has not fully complied with MPEP section 706.02(1)(2) which clearly addresses the statement required by applicant to overcome such rejection. Applicant further argues the pH ranges disclosed by the art of record and states that Nielsen actually teaches away from the claimed pH of 5.5-6.2.

It is the examiners position that Nielsen does however disclose saccharification at a pH of 5.5. It is noted that Nielsen additionally prefers 4.5, however clearly as disclosed by Nielsen a pH of 5.5 is sufficient. Saccharification processes are well known to those of ordinary skill in the art as exemplified by the art of record. Modifications/optimizations are apparent to those skilled in the art as is demonstrated by the ranges taught in each reference of record. Clearly applicants claimed pH of from 5.5 to 6.2 falls within the disclosed pH of 5.5. There is nothing of record to show that the disclosed pH of Nielsen teaches away from the claimed invention and that such pH would not result in a process of enzymatic saccharification as claimed by applicant. It is also important to note that the enzyme of Nielsen is derived from the claimed *A. niger* or *T. emersonii*.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20, 22, 23, 30-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-24 of U.S. Patent No. 6255084. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of both sets of claims are the same, i.e. drawn to a saccharification process comprising the use of a glucoamylase at temperatures ranging from 60-80 at a pH of 5.5 for 24-26 hours .

Claims 20-23,27,29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33,38,52 of copending Application No. 11/814,304. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of both sets of claims are the same, i.e. drawn to a saccharification process comprising the use of a glucoamylase at temperatures ranging from 60-70C at a pH of 5.5-6 for 0.5-1.5 hours .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 6/29/2009 have been fully considered but they are not persuasive.

In response to the ODP rejection over US patent 6255084, applicant merely states that the Examiner has mischaracterized the claims, however offers no explanation as to how the Examiner has mischaracterized such claims. The rejection is maintained.

In response to the ODP rejection over co-pending application 11/814304, applicant argues the expiry dates. Regardless, it is the Office's position that the claims in copending application overlap sufficiently with the claims of the instant application such that a Terminal Disclaimer is required.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Majunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

/Tiffany M Gough/
Examiner, Art Unit 1657